

REMARKS

Status of the Claims

Claims 20-28 are pending in the above-identified application. New claim 29 is herein added. Support for claim 29 can be found in the Specification at page 3, line 30. No new matter has been added.

Rejections under 35 U.S.C. § 103

The Examiner Rejects claims 20-28 under 35 U.S.C. § 103 as being unpatentable over Parikh et al. I & II (U.S. 2003/0017209 and U.S. 2004/0013723) in view of Tanimoto et al. (U.S. 5,447,732) and/or Yalpani (U.S. 2004/0063612) and Napolitano et al. (U.S. 5,496,558).

The invention is directed to a method of treating xerostomia comprising administering a sialogogue composition comprising polyglutamic acid having an average molecular weight of 10,000 to 5,000,000 Daltons or a salt thereof and a carrier.

A sialogogue is a composition which promotes salivary secretion. Salivary secretion can be stimulated in multiple ways, one of which is in response to a good taste.

The Examiner asserts that “[p]olyglutamic acid of the salt form of MSG is simply > 1 molecule of the same. Thus, if a single molecule works as a sialogogue, the skilled artisan would know that more than one molecule would also (e.g., any form of polyglutamic acid)” (Office Action, page 6). Applicants respectfully submit that MSG and polyglutamic acid are significantly different in multiple ways.

First, MSG and polyglutamic acid have a different structure. The effect of these different structures has been completely ignored by the Examiner in asserting obviousness. By their size alone, MSG and polyglutamic acid would be expected to have significantly different properties. In particular, claims 20, 21, and 28 all recite that the average molecular weight is between 10,000 and 5,000,000 Daltons. The interaction of these molecules with receptors and/or other chemicals

in vitro and *in vivo* would be expected to be different from that of a small molecule such as MSG.

Also, the two compositions act as sialogogues through different mechanisms. MSG is known to have a delicious taste. Salivary secretion can be stimulated by pleasant tastes.

However, polyglutamic acid has no taste, as described in the Specification at page 2, line 22, and page 10, Table 22. Accordingly, the mechanism by which polyglutamic acid acts as a sialogogue is different than that of MSG. For this reason, one of skill in the art would not find the use of polyglutamic acid as a sialogogue obvious in view of the disclosure of the use of MSG as a sialogogue. Stated another way, when the prior art understood that MSG acted as a sialogogue, a person skilled in the art with that knowledge would not be motivated to use a tasteless compound (polyglutamic acid) as a sialogogue.

In addition, the fact that polyglutamic acid or its salt acts as a sialogogue (*i.e.*, promotes salivary secretion or a moisturizing effect) is not disclosed in Tanimoto, Yalpani, and Napolitano. Thus, the combination of the prior art does not teach every element of the claimed method as it fails to teach that polyglutamic acid promotes salivary secretion. Applicants request that the rejection be withdrawn.

Furthermore, it is an unexpected benefit that the claimed composition is tasteless, especially when MSG has such a distinctive taste. The Specification points out that the use of many sialogogues is limited by their taste (Specification, page 2, line 5-6), thereby distinguishing the presently claimed invention from sialogogues that generate saliva secretion by taste. Applicants submit that the fact that polyglutamic acid is tasteless is an unexpected result which overcomes any showing of *prima facie* obviousness that may have been established. For this additional reason, Applicants request that the rejection be withdrawn.

Conclusion

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections, and suggest that the claims are in a condition for allowance.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Gerald M. Murphy, Jr. Reg. No. 28,977 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

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